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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,437	10/15/2001	Jeffrey A. Heroux	2528-8	3932

22852 7590 07/08/2005

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EXAMINER	
CHUNDURU, SURYAPRABHA	
ART UNIT	**PAPER NUMBER**
1637	

DATE MAILED: 07/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/976,437	HEROUX ET AL.	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *45-69 and 77-88* is/are pending in the application.

4a) Of the above claim(s) *77-80* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *45-69 and 81-88* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S.D.

DETAILED ACTION

1. Applicants' response to the office action filed on April 28, 2005 has been entered.

Status

2. Claims 1-44, 70-76 are cancelled. New claims 81-88 are added. Claims 45-69, 81-88 are pending. Claims 77-80 are withdrawn from consideration as being non-elected group. All arguments have been fully considered and thoroughly reviewed, and are deemed persuasive for the reasons that follow. This action is made FINAL necessitated by amendment.

New Grounds of Rejections necessitated by Amendment

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 45-54, 65-69, 81-82, 85-88 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)".

Here, the new limitation of "at a differing rate in the presence or absence of said activity, wherein said activity is not part of the product" in the claims 45-46, 50, appears to represent new matter. After a careful review of the specification, it is noted that this limitation was not present,

in the instant specification. Thus the limitation as recited lacks descriptive support in the specification.

Since no basis has been found to support the new claim limitation in the specification, the claims are rejected as incorporating new matter.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim interpretation: In the following rejections the activity that modifies the rate of joining (binding) of a first substrate with a second substrate to form a product" is given broadest reasonable interpretation as the binding activity of the two substrates to form a product" , thus the activity is dependent on the product produced. Thus the measuring of luminescence from the

binding complex is correlated to the activity that modifies the rate of joining (binding) to form a product.

A. Claims 45-47, 50-69, 81-88 are rejected under 35 U.S.C. 102(b) as being anticipated by Leland et al. (EP 0 570518).

Leland et al. teach a method of claims 45-46, of assaying a sample for an activity that modifies the rate of joining (binding activity) that joins (binds) a first substrate (an assay-performance substance) and a second substrate (a particle capable of binding with the sample analyte) to form a product (binding complex) comprising:

(a) forming a composition comprising said sample, said first and second substrate (see page 6, lines 10-19);

(b) incubating said composition to form said product (see page 6, line 21);

(c) immobilizing a luminescent label linked to said product on an electrode (see page 6, lines 22-23);

(d) applying a voltage at said electrode to induce luminescent label to emit luminescence (see page 6, line 23-24);

(e) measuring emitted luminescence to measure said activity (see page 6, line 25-26).

With regard to claim 46, 57, 85, Leland et al. teach that said first substrate is linked to a luminescent label (see page 9, line 48-58, page 10, line 1-7) and said second substrate linked to electrode (see page 10, line 56-58, page 11, line 1-7);

With regard to claim 47, 50, 81-84, Leland et al. teach that the second substrate is linked to said electrode via avidin (capture moiety) biotin linkage (see page 15, line 44-46);

With regard to claims 52-53, 62-63, Leland et al. teach that said first substrate comprises peptides and nucleic acids (see page 9, line 48-57);

With regard to claim 55-56, 60, 86, Leland et al. teach

(a) forming a composition comprising said sample and said substrate (see page 32, line 6-16);

(b) incubating said composition under conditions wherein said activity can cleave said substrate (see page 32, , line 17, page 11, line 36-52, indicates separation or cleaving , wherein amine acts as a reducing agent);

(c and d) immobilizing a luminescent label on an electrode not a carbon electrode and separating said substrate from said composition by inducing luminescence (see page 32, line 18-21, page 13, line 34-40, indicating gold, platinum electrodes);

(e) measuring emitted luminescence to measure the activity (see page 32, line 22-23);

With regard to claims 58-59, Leland et al. teach said electrode is further linked to one or more additional substrates forming a patterned array on the electrode or electrodes comprising at least two regions that contain substrates that differ in structure (see page 29, line 2-44, indicating different probe arrays);

With regard to claims 51, 61, 64, 87-88, Leland et al. teach that said activity results in cleavage of a covalent bond and said activity is selected from the group consisting of proteases (see page 11, line 36-52, indicates oxidation-reduction reactions which inherently include covalent bond, page 20, line 34-50);

Thus the disclosure of Leland et al. meets the limitations in the instant claims.

B. Claims 45-54, 65-69, 81-82, 85, 87-88 are rejected under 35 U.S.C. 102(e) as being anticipated by Massey et al. (USPN. 5, 866,434).

Massey et al. teach a method of claims 45-46, 50, of assaying a sample for an activity that modifies the rate of joining (binding activity) that joins (binds) a first substrate (an assay-performance substance) and a second substrate (a functionalized graphic nanotube) to form a product (binding complex) comprising:

(a) forming a composition comprising said sample, said first and second substrate (see col. 13, line 9-19, line 31-43);

(b) incubating said composition to form said product (see col. 13, line 20-22, line 44-45);

(c) immobilizing a luminescent label linked to said product on an electrode (see col. 13, line 15-22, line 31-45);

(d) applying a voltage at said electrode to induce luminescent label to emit luminescence (see col. 13, lines 24-27, line 48-51);

(e) measuring emitted luminescence to measure said activity (see col. 13, line 29-31, line 52-54).

With regard to claim 46-47, 85, Massey et al. teach that said first substrate is linked to a luminescent label (see col. 13, line15-17) and said second substrate linked (attached) to electrode (magnetically responsive nanotubes) (see col. 13, line 18-19);

With regard to claim 47, 50, 81-82, Massey et al. teach that the second substrate is linked (attached) to said electrode via avidin (capture moiety) biotin linkage (see col. 40, line 41-50);

With regard to claims 48-49, Massey et al. teach that said electrode (nanotube fibrils) linked to one or more additional substrates forming a patterned array of substrates comprising at least two substrates that differ in structure (see col. 52, line 27-67, col. 53, line 1-2, wherein

nanotube fibril comprises biotinylated fibril and alkylated biotinylated fibrils having two different structures);

With regard to claims 52-53, Massey et al. teach that said first substrate comprises peptides and nucleic acids (see col. 16, line 45-64);

With regard to claim 51, Massey et al. teach that said activity (binding activity) results in the formation of a covalent bond (see col. 10, line 13-37, wherein the complex formed with Y indicates a covalent bond);

With regard to claim 67, Massey et al. teach said electrode comprises conductive particles with in or on a polymeric material (see col. 11, line 47-67, col. 12, lines 1-28);

With regard to claims 54, 68, 87, Massey et al. teach that said activity is an enzyme activity comprising catalytic enzymes as glucosidases, dehyrogenases (see col. 47, line 10-15, col. 49, line 55-67, col. 50, line 1-67);

With regard to claim 65-66, said electrode comprises elemental carbon in the form of graphite (see col. 13, line 18-19);

With regard to claims 69, 88, Massey et al. teach that the method further comprises an inhibitor (reductant) and said activity is correlated to the amount of inhibitory ability of the inhibitor (see col. 14, line 3).

Thus the disclosure of Massey et al. meets the limitations in the instant claims.

Response to arguments:

4. Applicants' arguments and amendment are fully considered and found persuasive.

5. Applicant's arguments with respect to claims 47, 57, rejected under 35 USC 112 second paragraph as indefinite, have been considered and the rejection is withdrawn in view of the amendment.

6. Applicant's arguments with respect to claims 45-47, 50, 52-53, rejected under 35 USC 102(b) as anticipated by Leland et al. have been considered but are moot in view of the amendment and new ground(s) of rejection. Applicants' arguments are found unpersuasive because the new limitation reciting that the activity is not the part of the product does not exclude the broad scope of the claims and the activity that modifies the binding or joining two substrates to form a product, inherently teaches that the rate of binding activity is dependent on the product formed and the measurement of emitted luminescence from the binding complex is correlated to the activity of the rate of joining or binding. Thus the rejection is rewritten to include new limitation.

7. Applicant's arguments with respect to claims 45-76, rejected under 35 USC 102(e) as being anticipated by Massey et al. have been considered but are moot in view of the amendment and the new ground(s) of rejection. Applicants' arguments are found unpersuasive because the new limitation reciting that the activity is not the part of the product does not exclude the broad scope of the claims and the activity that modifies the binding or joining two substrates to form a product, inherently teaches that the rate of binding activity is dependent on the product formed and the measurement of emitted luminescence from the binding complex is correlated to the activity of the rate of joining or binding. Thus the rejection is rewritten to include new limitation.

Conclusion

No claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Suryaprabha Chunduru
Examiner
Art Unit 1637

JEFFREY FREDMAN
PRIMARY EXAMINER
7/7/05